In the United States Court of Federal Claims

No. 14-233C
(Filed: June 26, 2014)
***Order originally filed under seal April 28, 2014**

ARKRAY USA, INC.,	)
Plaintiff,	)
v.	)
THE UNITED STATES,	)
Defendant,	)
and	)
ABBOTT DIABETES CARE SALES CORPORATION,	)
Defendant-Intervenor.	)

ORDER GRANTING-IN-PART AND DENYING-IN-PART PLAINTIFF'S MOTION TO COMPLETE AND/OR SUPPLEMENT THE ADMINISTRATIVE RECORD

In this post-award bid protest case, ARKRAY USA, Inc. ("plaintiff" or "ARKRAY"), challenges the Defense Health Agency's ("DHA" or "the agency") selection of Abbott Diabetes Care Sales Corporation's ("Abbott" or "defendant-intervenor") self-monitoring blood glucose system ("SMBGS") test strips ("strips") for

the TRICARE formulary,[1] and its establishment of a blanket purchase agreement ("BPA") with Abbott alone for the purchase of the strips.

Plaintiff asserts that Abbott was ineligible for award because, among other things, Abbott's bid did not comply with the solicitation's requirement that Abbott have in place a process to supply, at no cost, blood glucose meters that comply with the Trade Agreements Act ("TAA").[2] Specifically, plaintiff contends that DHA should have eliminated Abbott from consideration because, at the time Abbott submitted its bid, Abbott was manufacturing its meters in China, a non-TAA country. Plaintiff asserts that, due to DHA's bias in favor of Abbott, DHA refused to enforce the TAA requirement when evaluating Abbott's bid.

Pending before the court is plaintiff's motion to complete/supplement the administrative record with documents that plaintiff argues address DHA's views and application of the TAA requirements in connection with this procurement. Specifically, plaintiff seeks to complete the administrative record with (1) all internal agency communications relating to the TAA or Federal Supply Schedule ("FSS") requirements applicable to the SMBGS BPA;[3] (2) all photographs of the meters provided by Abbott to

[1] The formulary is the approved list of pharmaceutical agents that must be available to eligible beneficiaries under the TRICARE pharmacy benefits program. Administrative Record ("AR") 1836.

[2] Where applicable, the TAA generally prohibits the federal government from procuring products from a foreign country that has not signed a reciprocal agreement on government procurement. See 19 U.S.C. § 2512.

[3] Plaintiff's request for additional internal communications related to FSS requirements applicable to the SMBGS BPA is **DENIED** because DHA relied upon a Department of Veterans

the agency during any part of the evaluation process;[4] (3) notes, minutes, and/or agendas from the June 20, 2013 industry teleforum regarding the SMBGS BPA solicitation;[5] (4) a copy of the FSS contract for Abbott as of the date of Abbott's submission of its proposal for the SMBGS BPA on July 11, 2013, and any documents relating to Abbott's satisfaction of this BPA requirement;[6] and (5) any post-award notes, minutes, and/or agendas from the meetings between Abbott and the Agency held on November 20, 2013 and November 25, 2013, as well as any correspondence between Abbott and the agency regarding these meetings.

On April 14, 2014, the court set a briefing schedule for plaintiff's motion to complete/supplement the administrative record, and ordered the government to provide

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Affairs pharmaceutical database and a contract modification, printouts of which are already included in the record. These documents speak for themselves. See note 6.

[4] In its opposition brief, the government represented that there are no photographs of meters provided by Abbott to the government during the procurement process other than those that are already included in the administrative record. Because the record is complete in this regard, there is no relief available.

[5] In its opposition brief, the government represented that it had inadvertently excluded notes from the June 20, 2013 meeting from the administrative record. On April 21, 2014, the court granted the government's motion to amend/correct the record so as to include an additional page of handwritten notes from that meeting. Order, ECF No. 41. Accordingly, plaintiff's motion to supplement the record with notes from the June 20, 2013 meeting is **DENIED** as moot.

[6] In its opposition brief, the government represented that the agency did not rely on the FSS contract for Abbott in making its decision to select Abbott for the BPA. Specifically, the government represents that the agency primarily relied upon a public Department of Veterans Affairs pharmaceutical database, which reflects FSS status. The government further represents that the agency only used Abbott's FSS contract to verify the status of one of Abbott's proposed test strips, and that a printout of this verification is included in the administrative record at pages 1522-23. The court is satisfied that the government has provided the necessary materials related to Abbott's satisfaction of the FSS requirement. Accordingly, plaintiff's motion to supplement the record with a copy of the FSS contract or other FSS-related materials is **DENIED**.

the court with a copy of all documents requested in plaintiff's motion (if in existence) to allow for in camera review. Order, ECF No. 35. On April 18, 2014, the government hand-delivered to the court a set of documents that it represents reflect all available documents responsive to plaintiff's motion. See Notice, ECF No. 37. The government divided these documents into two categories: pre-award documents and post-award documents. Briefing on plaintiff's motion was completed on April 25, 2014, and the court deems oral argument to be unnecessary. For the reasons explained below, plaintiff's motion is **GRANTED-IN-PART** and **DENIED-IN-PART**.

I. BACKGROUND[7]

Pharmaceutical agents are selected for inclusion in the TRICARE formulary based upon their relative clinical and cost-effectiveness, as determined by a Pharmaceutical and Therapeutics Committee ("P&T committee"), composed of representatives of pharmacies of the uniformed services facilities and other military healthcare providers. 10 U.S.C § 1074g(b). Before formulary decisions are made, a Beneficiary Advisory Panel ("BAP"), including representatives of beneficiaries, contractors, and providers, has an opportunity to comment on any proposed changes to the formulary. 10 U.S.C. § 1074g(c). The DHA Director makes final formulary decisions, taking into account both the P&T committee's recommendations and the BAP's comments. Id. §§ (a)(2)(A)-(D), (c); 32 C.F.R. §

[7] A brief review of the formulary approval process and history of the BPA competition is necessary to appreciate why some of the materials sought by plaintiff are necessary to either complete or supplement the record and allow for effective judicial review. Accordingly, this order only recites those facts that are essential to resolving plaintiff's motion to supplement the administrative record.

199.21(g)(3). Sometime after approval of the formulary decision, an agency Contracting Officer signs one or more BPAs with participating pharmaceutical suppliers.

On May 15, 2013, the P&T committee reviewed the relative clinical effectiveness of over 100 brands of blood glucose test strips. See AR 1718-19, 1838. Based upon that review, the committee recommended a number of minimum requirements, including that "SMBGS test strips eligible for inclusion on the Uniform Formulary must be . . . compliant with the Trade Agreements Act. Corresponding SMBGS glucometers must also be compliant with the Trade Agreements Act. Manufacturers of SMBGS glucometers will be required to provide DoD beneficiaries with a no-cost glucometer." AR 252-53, 358. Due to these recommendations, the agency decided not to include [. . .], which manufactured meters in China (a non-TAA country), in the pool of seven potential formulary candidates identified.[8] AR 349, 1838. On June 13, 2013, the agency posted a solicitation for glucose test strips on its website. Under the heading "General Requirements," the solicitation stated:

> Meters
> - Manufacturer must have a process to supply meters to beneficiaries at no cost.
> - Must be Trade Agreement Act-compliant

AR 200.

On June 18, 2013, an Abbott employee e-mailed DHA with questions for an upcoming industry teleforum regarding the SMBGS BPA solicitation. AR 1010. Specifically, Abbott inquired as to why the glucometers must be TAA-compliant:

[8] The "final candidates" included Abbott, [. . .], ARKRAY, and [. . .]. AR 403.

"Historically meters have been provided by SMBGS vendors at no cost to TRICARE patients. It is also a requirement of the UF BPA Appendix as well. Why must meters that are provided at no cost to the government . . . be TAA compliant?" Id. Two days later, that same Abbott employee e-mailed several DHA employees involved in the solicitation seeking a 15-minute meeting, although the e-mail refrains from stating the purpose of the meeting. AR 1014. The record is silent as to whether that meeting occurred or its purpose.

Ultimately, five vendors submitted quotes, including ARKRAY and Abbott. AR 1840. Abbott submitted its bid to DHA on or about July 21, 2013. AR 227. With regard to the TAA-compliance of its meters, Abbott's proposal stated:

> **1. Must be Trade Agreement Act-compliant (TAA)**
> Abbott Diabetes Care manufactures meters in a TAA nation. Following is the physical address of the manufacturing location:
>
> Flextronics Manufacturing (S) Pte Ltd
> 1 Kallang Place
> Singapore 339211

AR 1085 (emphasis in original). Notwithstanding this statement, it is undisputed that at the time Abbott submitted its BPA price quote, Abbott "sold meters made in China in the U.S. market, and had not yet imported meters manufactured in Singapore for distribution to the Agency." Intervenor's Opp. to Pl.'s Mot. to Supplement 6. Abbott claims, however, that when it submitted its bid, Abbott was "in the process of manufacturing meters in Singapore that would comply with the BPA requirement." Id.

At its August 2013 meeting, the P&T committee reviewed the cost information provided in the offerors' quotes and concluded that Abbott's test strips were the most cost

effective. AR 570-72. Accordingly, the P&T committee recommended that Abbott's strips be designated as the only strips available on the formulary. Id. On September 16, 2013, Abbott and DHA participated in a teleconference in which Abbott revealed that it was not yet producing all of its meters in a TAA compliant country. Meeting minutes from that teleconference state as follows:

> -meters- [Abbott] standing up a brand new production line for this implementation; will be in a TAA compliant location (Singapore) -- large undertaking for Abbott -- need fair amount of lead time, to make sure things are done correctly – all or nothing, not a ramp up
>
> –They will have an amount of TAA compliant meters read[y] to go in Nov, but not [. . .]
>
> -need things built and in place to do a successful implementation
>
> . . .
>
> -want to ensure all [patients] get TAA compliant meter; meters at MD offices/retail outlets are currently non-TAA compliant
>
> . . .
>
> Dave question on implementation – by law have 180 days – which is May 1st
>
> -Jeremy-asked why they told us 4-6 months, and now need 6 [months]
>
> -Abbott-conversion for [Medical Treatment Facilities] is 6 months
>
> . . .
>
> -May 1st only an issue if dod wants Abbott to send meters to [patients]

AR 2050-51. The meeting notes further discuss Abbott's plan to make TAA-compliant meters.

The P&T committee's recommendation to select Abbott as the sole test strip provider was made public at a September 19, 2013 BAP meeting. The BAP agreed with the recommendation that Abbott be the sole manufacturer listed on the formulary, but recommended a longer implementation period to reduce the risk of complications while coordinating the medical benefits with new and existing patients. AR 639-44.

On September 27, 2013, ARKRAY filed a protest with the Government Accountability Office ("GAO") in which it challenged the selection of Abbott for the formulary. Arkray USA, Inc., 2014 CPD ¶ 90 (Comp. Gen. Mar. 5, 2014). On September 30, 2013, ARKRAY withdrew its protest after being informed that a final decision had not yet been made with regard to the formulary. On November 7, 2013, the DHA Director approved the P&T committee's recommendations (as modified by the BAP), AR 644, and the government's Contracting Officer signed the BPA with Abbott on November 12, 2013, AR 692. ARKRAY re-filed its protest with the GAO on November 25, 2013. AR 1-112. GAO denied the protest on March 5, 2014. AR 1834.

II. DISCUSSION

a. Standard of review

It is well-established that "the focal point for judicial review should be the administrative record already in existence" at the time of the agency's decision. Axiom Res. Mgmt., Inc. v. United States, 564 F.3d 1374, 1379 (Fed. Cir. 2009) (quoting Camp v. Pitts, 411 U.S. 138, 142 (1973)); Optimization Consulting, Inc. v. United States, 115 Fed. Cl. 78, 90-91 (2013). A complete record is one that "contains the information relied upon by the agency as it made its decision, as well as documentation of the agency's decision-making process." Kerr Contractors, Inc. v. United States, 89 Fed. Cl. 312, 335 (2009), aff'd, 374 F. App'x 979 (Fed. Cir. 2010). This court's rules include a non-exhaustive list of "core documents" relevant to a bid protest.[9] Joint Venture of Comint

[9] As the court explained in Allied Tech. Grp., Inc. v. United States, whether or not previously omitted Appendix C materials should be added to the administrative record is a question left to

Sys. Corp. v. United States, 100 Fed. Cl. 159, 166 (2011). Among these core documents are (1) the agency's responses to any questions about or requests for clarification of the solicitation; (2) correspondence between the agency and the protester, awardee, or other interested parties relating to the procurement; (3) records of any discussions, meetings, or telephone conferences between the agency and the protester, awardee, or other interested parties relating to the procurement, (4) documents relating to any pre- or post-award debriefing; and (5) documents relating to any stay, suspension, or termination of award or performance pending resolution of the bid protest. See Rules of the United States Court of Federal Claims ("RCFC") Appendix C ¶ 22 ("Paragraph 22"). Documents such as these "presumptively qualify for inclusion in the Administrative Record." Dyncorp Int'l LLC v. United States, 113 Fed. Cl. 298, 303 (2013).

In Axiom, the Federal Circuit clarified that supplementation of the administrative record with materials other than those listed above "should be limited to cases in which the omission of extra-record evidence precludes effective judicial review." 564 F.3d at 1380 (internal quotation omitted). In this connection, a distinction must be drawn between supplementing the administrative record and completing the record. Linc Gov't Servs., LLC v. United States, 95 Fed. Cl. 155, 158 (2010). Where a party seeks to add evidence to the record that consists of materials that were generated or considered by the agency during the procurement and decisionmaking process, such a request is properly

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the sound discretion of the court. 92 Fed. Cl. 226, 230 (2010) (excluding post-award declarations because they had first been offered by plaintiff as part of its GAO protest).

viewed as a request to complete—rather than supplement—the administrative record, see Comint, 100 Fed. Cl. 159, 167, and the court will ordinarily order the agency to complete the administrative record by adding pre-award records.

Supplementing the administrative record raises different concerns from simply completing the record. Supplementing the record with materials not before the agency or with documents that post-date the decision is only allowed when it is necessary for judicial review. Axiom, 564 F.3d at 1381. Thus, courts must "exercise restraint when considering whether or not to supplement the administrative record." Office Depot, Inc. v. United States, 94 Fed. Cl. 294, 296 (2010). Supplementation may be appropriate, however, where the record raises serious questions concerning the rationality of the award decision, Impresa Construzioni Geom. Domenico Garufi v. United States, 238 F.3d 1324, 1341 (Fed. Cir. 2001); Office Depot, 94 Fed. Cl. at 298, or where the additional evidence is likely probative of potential agency bias or bad faith, see L-3 Commc'ns Integrated Systems, L.P. v. United States, 91 Fed. Cl. 347, 356 (2010).

Against this backdrop, the court turns to plaintiff's motion to complete/supplement the record.

b. The government shall complete the administrative record with the pre-award materials submitted to the court

The pre-award documents provided by the government that are responsive to plaintiff's request include (1) a March 2013 e-mail between government officials concerning contract requirements for the SMBGS BPA; (2) pre-award handwritten notes from a May 7, 2013 government meeting; (3) pre-award handwritten notes from a May

14, 2013 government "pre-brief" meeting concerning the SMBGS BPA's contract requirements; and (4) a September 19, 2013 e-mail from an Abbott employee to the government, which references a schedule for providing TAA-compliant meters.[10] The government contends that even if these materials fall within the scope of Paragraph 22, the court should exclude these materials because they are not necessary to permit effective judicial review. For the reasons explained below, the court disagrees.

Having reviewed each of the documents in camera, the court finds that all of these materials were either generated or considered by the agency during the procurement and decisionmaking process, and that they are necessary to complete the administrative record.[11] Comint, 100 Fed. Cl. at 167. Moreover, these documents are relevant to the key issue in this case: the agency's understanding and application of the TAA requirement. For example, notes from the May 14, 2013 "pre-brief" meeting include the following notations:

> David Hunt -Can't buy non-TAA meter even if disguised as a gift
> -will we buy [. . .] strips in [indecipherable]
> Shana -Would [. . .] win a protest if they protest?
> -David says no

(emphasis in original). These statements go to the agency's understanding and application of the TAA-requirement, and could be viewed as corroborating plaintiff's

[10] Given that the DHA Director did not approve Abbott's selection until November 7, 2013, the court assumes that the government inadvertently labeled the September 19, 2013 e-mail as a post-award document.

[11] Indeed, the court is puzzled why the government would contest the inclusion of the September 19, 2013 e-mail, which plainly constitutes "correspondence between the agency . . . and the awardee concerning the procurement." Appendix C ¶ 22. The e-mail is presumptively part of a complete record in a bid protest.

allegations concerning whether DHA enforced the solicitation's requirements in a biased fashion. Accordingly, the court **ORDERS** the government to add all of the pre-award materials to the administrative record.

c. The government shall complete the administrative record with the post-award materials that it submitted to the court

The post-award documents provided by the government that are responsive to plaintiff's motion include (1) an agenda for a post-award November 20, 2013 meeting with Abbott;[12] (2) a different version of the same agenda for the post-award November 20, 2013 meeting, which includes handwritten notes; (3) six pages of handwritten notes from the November 20, 2013 meeting with Abbott;[13] and (4) a November 27, 2013 e-mail from an Abbott employee to the government. The government argues that these materials should be excluded as either unnecessary for judicial review or on the grounds that they were not before the agency at the time of the decision. For the reasons explained below, the court disagrees.

As noted, under RCFC Appendix C ¶ 22(s), "documents relating to any stay, suspension, or termination of award or performance pending resolution of the bid protest" are presumptively included as part of a complete administrative record. Dyncorp Int'l,

[12] The agenda includes the following disclaimer:

> DoD just cannot issue orders under the BPA while under protest. This does not [i]nhibit the actions of Abbott and there is nothing wrong with Abbott being prepared as long as you understand that it is at your risk as we do not know if the protests will be sustained or denied. Providing the PEC with updates during the protest period is acceptable and is in the best interest of the Government.

[13] These notes include the following notation: "[Patient] letters => wait until [indecipherable] protest is resolved."

113 Fed. Cl. at 303. The court begins by observing that all of the post-award documents relate to the November 20, 2013 meeting at which Abbott and the government planned to discuss—and did discuss—the topic of Abbott's performance during the protest period. Although ARKRAY did not refile its GAO protest until November 25, 2013, the court holds that a protester that diligently pursues its protest should not be denied access to Paragraph 22 materials simply because the government and awardee happened to communicate during the brief period between the date of award and the protester's timely refiling of its protest.[14] These materials provide factual information related to Abbott's compliance with the TAA requirement, and there is no rational reason to exclude them when they complete the record. Accordingly, the court finds that these documents should be included in the record along with the pre-award documents.

Moreover, even if the court were to conclude that the post-award materials were not "core documents," the court would nevertheless order the government to supplement the administrative record on the grounds that these documents are needed to conduct effective judicial review. As noted, plaintiff seeks to add documents to the administrative record in order to corroborate its allegation that due to DHA failed to enforce the TAA requirement when evaluating Abbott's bid. In support, ARKRAY has marshaled considerable evidence related to Abbott's potential non-compliance with the TAA at the

[14] With one exception, all of the post-award materials provided by the government were created during the brief period between the September 30, 2013 withdrawal of ARKRAY's untimely protest and the November 25, 2013 re-filing of that protest. That one exception—the November 27, 2013 e-mail from Abbott to the government—plainly constitutes a document concerning performance during a protest, and is presumptively included as part of a complete administrative record.

time when bidding closed. Specifically, plaintiff has shown that (1) DHA excluded [. . .], another strip manufacturer, from further consideration in May 2013 because its meters were being manufactured in China; (2) shortly after DHA posted the solicitation, which included the TAA requirement, Abbott sought clarification from DHA as to the need for TAA compliant meters; (3) although Abbott certified that its meters were TAA-compliant, DHA knew, prior to award, that Abbott was still manufacturing meters in China and still in the process of standing up a brand new production line in a TAA-compliant country; (4) DHA officials questioned Abbott's ability to achieve delivery targets, and Abbott confirmed that it would be difficult to achieve a May 1, 2014 delivery date if the agency wanted Abbott to send meters to all patients; and (5) notwithstanding all of this information, the DHA Director selected Abbott as the sole test strip provider on November 7, 2013, and the Contracting Officer issued the BPA on November 12, 2013. Assuming that plaintiff is correct that the solicitation required offerors to possess a process to supply TAA-compliant meters as of the close of bidding, the aforementioned evidence suggests that there were questions involving Abbott's TAA-compliance that should have led to further inquiry by the government before award.

After reviewing the post-award materials provided by the government in camera, the court is satisfied that all of them are probative as to the agency's understanding and application of the TAA requirement.[15] For example, the notes from the November 20,

[15] In this connection, the court rejects the government's argument that these materials must be excluded because they constitute "deliberative discussions." Gov. Mot. 14 (citing Tafas v. Dudas, 530 F. Supp. 2d 786, 794 (E.D. Va. 2008)). These documents are typical of the documents the government already included in the record with regard to other potential offerors

2013 meeting clearly reference Abbott's strategy to comply with the TAA requirement. Specifically, the handwritten meeting notes include the following notations:

> OCONUS Meters
> -will ship non-TAA compliant meters?
> . . .
> Meter Voucher => Is it OK?
> . . .
> -Right now: [. . .] meters TAA compliant
> . . .
> Abbott
> -Don't want 1-800 # on the letter b/c of lack of TAA meters. That is the purpose of the voucher coupon

Including such materials in the record does not, as the government and defendant-intervenor contend, risk "convert[ing] the 'arbitrary and capricious' standard into effectively de novo review." Axiom, 564 F.3d at 1380 (quoting Murakami v. United States, 46 Fed. Cl. 731, 735 (2000)). Rather, given that that questions regarding TAA-compliance had been raised during the bid-evaluation process, these documents are necessary for the court to understand whether Abbott's bid satisfied the TAA requirement. Accordingly, even if these materials fell outside of Paragraph 22 "core documents," the court finds it is necessary to supplement the record with them to allow for effective judicial review.

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and are necessary for effective judicial review. Moreover, the government has not satisfied any of the procedural requirements for properly invoking the deliberative process privilege: neither an agency head nor an authorized delegate has asserted the privilege, the agency has not stated with particularity what information is to be excluded, and the agency has not provided the court with precise or certain reasons for maintaining the confidentiality. See Marriott Int'l Resorts, L.P. v. United States, 437 F.3d 1302, 1307 (Fed. Cir. 2006); Sikorsky Aircraft Corp. v. United States, 106 Fed. Cl. 571, 577 (2012); Walsky Const. Co. v. United States, 20 Cl. Ct. 317, 320 (1990).

III. CONCLUSION

For the foregoing reasons, plaintiff's motion to supplement the administrative record is **GRANTED-IN-PART** and **DENIED-IN-PART**.

IT IS SO ORDERED.

s/Nancy B. Firestone
NANCY B. FIRESTONE
Judge